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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

FEB 2 6 2010

The assigned 510(k) number is K092947.

Date:	January 25, 2010
Submitted by:	ScottCare Corporation Registration No: 1527715 4791 West 150th Street Cleveland, OH 44135
Contact Person:	Mr. Timothy J. Leyva 216-362-0550 # 113 216-264-6129 Fax tleyva@scottcare.com
Manufacturing Site:	ScottCare Corporation Registration No: 1527715 4791 West 150th Street Cleveland, OH 44135
Trade Name:	TeleSentry Wireless Ambulatory ECG Arrhythmia Monitor
Common Name:	Cardiac Event Monitor Mobile Cardiac Telemetry
Classification:	Arrhythmia Detector and Alarm (including ST-segment measurement and alarm) (21 CFR 870.1025)
Class:	Class II, Special Controls
Product Code:	DSI
Subsequent Product Code:	DRG
Legally Marketed Predicate Device(s):	Braemar Fusion Wireless – Ambulatory ECG Arrhythmia Monitoring System (K081444), July 31, 2008

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1. Device Description:

TeleSentry is a battery powered ambulatory ECG monitor which analyzes an electrocardiographic signal. The TeleSentry device classifies all detected heart beats and recognizes specific rhythm abnormalities. All detected results, including annotations for every detected heart beat and the ECG signals are securely transmitted via a cellular telephony network to a remote server. The server is accessible by a monitoring center for review and evaluation by trained qualified medical staff. The data transmission is automatically triggered when abnormalities are detected. The triggering criteria are based on physician's recommended pre-determined settings and adjustable thresholds programmed for brady, tachy, pause and afib events. The data will also be transmitted when manually triggered by the patient; or periodically if programmed for regular transmission. The TeleSentry device is equipped with sufficient memory and processing capacity to record the signal received from the sensor, even while in parallel, allowing interrogation of the device data or adjustment of triggering thresholds. The TeleSentry device records and stores the entire ECG full disclosure for up to 30 days on its internal storage card. When cellular service is not available, the monitoring center is immediately notified and data can be transmitted via land-line telephone using a USB connection or a Bluetooth connection, or via broadband internet connection.

2. Indications for Use:

The TeleSentry device is intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest non-lethal cardiac arrhythmia. The device continuously monitors and records the data, automatically records alarm events triggered by an arrhythmia detection algorithm or manually by the patient, and automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician.

Contraindications:

a. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
b. Patients who the attending physician thinks should be hospitalized.

3. Substantial Equivalence:

The TeleSentry device is technologically equivalent and identical to the predicate device except as specifically highlighted below:

	Predicate Device Braemar Fusion	**ScottCare TeleSentry**
RF transmission range	10 meters open space	100 meters open space
Acoustic Transmission	Yes	No
Bandwidth	0.5hz to 40Hz	0.5Hz - 100 Hz
Display	LCD	LED
Input Impedance	20 Mohm	>20 Mohm
12 Lead	No	Yes
Differential Input@ AC15HZ	is + 5mV p-p	+ / - 1mV p-p

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Differential Input Range	DC +/- 165mV	DC ± 100mV
Common Mode Ratio CMR)	60dB	92 dB
Battery Type	3.6V AA Disposable	3.7V lithium polymer rechargeable
Battery Life	7 days then disposed	24-36 hours before re-charge
Relative Humidity	30% to 85%	25% to 95% RH, nc
SPS	256	100,200,1000
Alarm-no connection	No	Yes

In each of these instances, the technology of the TeleSentry device meets or exceeds the operating specifications of the predicate device and they do not have any adverse impact on the safety and efficacy of the device as validated through our performance testing.

4 Referenced Standards and Performance Testing

The TeleSentry device was tested and meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- IEC 60601-1:1999 "Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995"
- IEC 60601-1-2:2001/AI:2004 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests" Class B
- AAM1/ANSI EC38:2007 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- AAMI / ANSI EC57:1998/(R)2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

5. Conclusion:

ScottCare's TeleSentry ECG device (K092947) is safe, effective and substantially equivalent to the predicate Braemar Fusion device (K081444) as supported by the descriptive information and the performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 2 6 2010

Scottcare Corporation
c/o Mr. Timothy Leyva
Director, Operations & Regulatory Affairs
4791 West 150th St.
Cleveland, OH 44135

Re: K092947
Trade/Device Name: TeleSentry
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (Special Controls)
Product Code: DSI, DRG
Dated: January 25, 2010
Received: January 26, 2010

Dear Mr. Leyva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

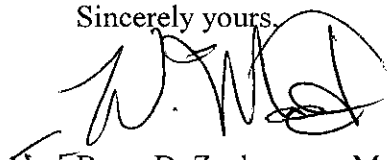
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092947

Device Name: TeleSentry

Indications for Use:

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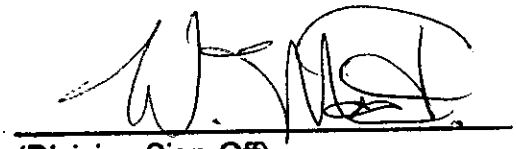
Contraindications:

a. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
b. Patients who the attending physician thinks should be hospitalized.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092947/S001